IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. _____**
	)	
CONGRESSIONAL SEAFOOD COMPANY, INC., a corporation, and STANLEY S. PEARLMAN, JONATHAN D. PEARLMAN, and STEPHEN G. BARDSLEY, individuals,	)	
	)	
Defendants.	)	
_____	)	

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by and through its undersigned attorneys, and for its Complaint against Defendants, alleges and represents as follows:

INTRODUCTION

1. This statutory injunction proceeding is brought pursuant to the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to enjoin and restrain the defendants from violating 21 U.S.C. § 331(a) by introducing or causing to be introduced into interstate commerce, or delivering or causing to be delivered for introduction into interstate commerce, food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4), and from violating 21 U.S.C. § 331(k) by causing food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such food is held for sale after shipment in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant Congressional Seafood Company, Inc. ("Congressional" or "the firm") is incorporated under the laws of the State of Maryland. Congressional does business at 7901 Oceano Avenue, Jessup, Maryland, which is in Howard County and within the jurisdiction of this Court. Congressional processes a variety of seafood products including, but not limited to: (1) fresh and frozen scombrotoxin-forming species and non-scombrotoxin-forming species of fish; (2) ready-to-eat products such as raw tuna fish for sushi/sashimi, fresh crabmeat, and vacuum packaged pasteurized crabmeat; (3) frozen seafood products, including octopus and shrimp; and (4) molluscan shellfish.

5. Defendant Stanley S. Pearlman, an individual, is the President and majority shareholder of Congressional. Mr. Pearlman performs his duties at 7901 Oceano Avenue, Jessup, Maryland, within the jurisdiction of this Court.

6. Defendant Jonathan D. Pearlman, an individual, is the Vice President and Director of Operations of Congressional. Mr. Pearlman is responsible for the day-to-day conduct of the business, including food safety, recalls, employee practices and training, and facility maintenance. He wrote the firm's Hazard Analysis and Critical Control Point (HACCP) plans. He has stated that he has the power and authority to detect, correct, and prevent violations at the firm. Mr. Pearlman performs his duties at 7901 Oceano Avenue, Jessup, Maryland, within the jurisdiction of this Court.

7. Defendant Stephen G. Bardsley, an individual, is the HACCP Coordinator of Congressional. Mr. Bardsley is responsible for ensuring that the firm processes seafood in accordance with the HACCP plans. He also monitors sanitation conditions and practices. Mr. Bardsley performs his duties at 7901 Oceano Avenue, Jessup, Maryland, within the jurisdiction of this Court.

8. Defendants have been, and are now, engaged in preparing, packing, holding, and distributing a variety of fresh, frozen, and ready-to-eat seafood products.

9. The Defendants deliver fresh, frozen, and ready-to-eat seafood products to locations in Maryland, Washington, D.C., Virginia, Pennsylvania, and New Jersey.

10. The defendants receive fresh and frozen seafood products from various suppliers in Louisiana, Florida, South Africa, and Vietnam.

HEALTH RISKS

11. Fresh, frozen, and ready-to-eat seafood products are well known sources of *Escherichia coli* (or E. coli), *Listeria monocytogenes*, and other pathogenic microorganisms. The production of fresh, frozen, and ready-to-eat seafood products without adequate HACCP plans poses a significant public health risk. Humans who consume food containing these bacteria can suffer serious health consequences.

12. For example, there are some strains of *Escherichia coli* that can cause severe illness, including abdominal cramps, bloody diarrhea, and nausea in healthy adults, and kidney damage that can lead to death in children, the elderly, and the immune-impaired. *Listeria monocytogenes* can cause listeriosis, an illness that, although it produces relatively mild symptoms in healthy individuals, can adversely affect pregnant women and result in miscarriage or stillbirth.

13. Ready-to-eat fish that is vacuum packaged is particularly susceptible to toxin formation by *Clostridium botulinum*. This type of packaging involves removing the oxygen from a product packed in an oxygen-impermeable container. Although this process extends the shelf life of a product by inhibiting the growth of many aerobic bacteria that provide visual signs of spoilage, *Clostridium botulinum* is anaerobic, i.e., it grows in the absence of oxygen. The product's extended shelf life can provide the time for the organism to grow before other bacteria would provide visual evidence to the consumer that the product has spoiled. If ingested, the potent neurotoxin produced by *Clostridium botulinum* may result in paralysis of the diaphragm and chest muscles, leading to the inhibition of respiration and possible death from asphyxiation. Although the incidence of this is very low, there is a high mortality rate if treatment is not prompt and appropriate.

14. Furthermore, processing fresh and frozen scombrotoxin-forming species without developing and implementing an adequate HACCP plan can lead to scombrotoxin formation in the fish. Scombrotoxin poisoning is caused by the consumption of fish containing elevated levels of compounds, most notably histamine, created by bacteria in fish that are not stored at sufficiently low temperatures. Once histamine is formed, it cannot be eliminated by heat or freezing. The symptoms of scombrotoxin poisoning include allergic-type reactions, such as dizziness, nausea, and headaches. Individuals suffering severe cases of scombrotoxin poisoning can suffer from blurred vision, respiratory distress, and swelling of the tongue. In severe cases involving the elderly, the very young, or the immune impaired, scombrotoxin poisoning may require hospitalization.

15. There are also many pathogens—such as *Salmonella spp.*, some strains of E. coli, *Campylobacter jejuni*, hepatitis A virus, and Norwalk virus—that are of particular concern in raw and

ready-to-eat seafood products because they originate in sewage or animal sources. These pathogens can be present on incoming product or can be transferred to products through cross-contamination during processing. Their presence is dependent upon, among other things, how the raw material was handled before it was delivered to the processor and the effectiveness of the firm's in-plant sanitation program.

16. Humans who consume food containing these pathogens can suffer serious health consequences. For example, *Salmonella spp.* can cause fevers, abdominal cramps, and dehydration. *Campylobacter jejuni*, Hepatitis A virus, and Norwalk virus can cause abdominal pain, vomiting, diarrhea, dehydration, and fever. These pathogens may become life-threatening in the young, the elderly, and the immune-compromised if dehydration is ignored or not treated.

17. In the production of commercially processed ready-to-eat products intended for raw consumption, such as sushi, there are no processes applied, such as cooking, to eliminate any pathogens present on the incoming product. Therefore, strict in-plant sanitation measures must be instituted to prevent cross-contamination and the proliferation of environmental contaminants in the plant. In addition, the product must be refrigerated to prevent any significant growth.

18. Even if seafood products are intended to be cooked, adequate sanitation is needed to prevent pathogens from persisting in the plant over time, which can result in the spread of pathogens throughout the distribution system to vehicles used to transport product, retail stores, restaurants, and consumer homes where they may contaminate ready-to-eat products.

19. The United States Food and Drug Administration ("FDA") has conducted several inspections of the Defendants' facility, all of which documented the defendants' consistent pattern of violative food processing practices.

STATUTORY AND REGULATORY PROVISIONS

20. The defendants' seafood products are articles of food within the meaning of 21 U.S.C. § 321(f).

21. The defendants violate 21 U.S.C. § 331(a) by introducing or causing the introduction, or delivering or causing the delivery for introduction, into interstate commerce of seafood products that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

22. The defendants violate 21 U.S.C. § 331(k) by causing seafood products that are held for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

23. The defendants adulterate their seafood products within the meaning of 21 U.S.C. § 342(a)(4), in that food is being prepared, packed, and held under insanitary conditions whereby it may be rendered injurious to health.

24. The defendants have failed to follow the seafood HACCP regulations, in violation of 21 C.F.R. Part 123. Therefore, the food is adulterated within the meaning of 21 U.S.C. § 342(a)(4). See 21 C.F.R. § 123.6(g).

25. Under the requirements of 21 C.F.R. § 123.6(a), every processor of fish and fishery products, such as the defendants, must "conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur" during the processing of each kind of fish or fishery product that it produces. Whenever a hazard analysis identifies one or more food safety hazards that are reasonably likely to occur, such processor must, pursuant to 21 C.F.R. § 123.6(b), develop and implement an adequate HACCP plan to control the identified food safety hazard(s).

26. A food safety hazard is "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." 21 C.F.R. § 123.3(f).

27. The defendants have failed to develop, implement, and verify an adequate HACCP plan for each type of seafood product that they process. See 21 C.F.R. § 123.6(b). Without an adequate HACCP plan for each type of product, there is no assurance that pathogens will be prevented from developing in the product.

28. To avoid the development of pathogens in their seafood products, the defendants must establish critical limits of temperature controls at the critical control points of receiving and storing the seafood products. Once adequate critical limits have been established, the defendants must develop and implement adequate written process monitoring, equipment verification, and corrective action plans to ensure that the critical limits are consistently met at the critical control points.

29. A "critical limit" is the "maximum or minimum value to which a physical, biological, or chemical parameter must be controlled" at a point in a food process when a food hazard can be prevented. 21 C.F.R. § 123.3(c). A "critical control point" is a "point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." 21 C.F.R. § 123.3(b).

THE DEFENDANTS' CONDUCT AND VIOLATIONS

30. FDA has conducted four inspections of the defendants' facility: May 12-22, 2009; September 25-October 3, 2006; May 10-12, 2005; and September 8-9, 2004. All of the inspections documented the defendants' consistent pattern of violative food processing practices.

31. FDA's inspections show that the defendants have an extensive history of not developing or

implementing adequate written HACCP plans for each type of seafood product that they process, as required by 21 C.F.R. § 123.6.

THE MAY 2009 INSPECTION

32. FDA conducted the most recent inspection of Congressional on May 12-22, 2009. During this inspection, the FDA investigator observed and documented significant violative conditions on a List of Inspectional Observations ("Form FDA-483") including, but not limited to, the following:

a. The defendants have failed to implement the record keeping system that documents the monitoring of the critical control points for processing fresh scombrotoxin-forming and non-scombrotoxin-forming species to control the food safety hazards, such as pathogen growth, that are likely to occur, in violation of 21 C.F.R. § 123.6(c)(7);

b. The defendants have failed to implement appropriate corrective actions after a deviation from a critical limit occurs for all seafood products, in violation of 21 C.F.R. § 123.7;

c. The defendants have not adequately verified their HACCP plans by performing an adequate record review, in violation of 21 C.F.R. § 123.8(a)(3);

d. The defendants have failed to monitor sanitation conditions and practices during processing with sufficient frequency to ensure compliance with current good manufacturing practice requirements specified in 21 C.F.R. § 110, in violation of 21 C.F.R. § 123.11(b);

e. The defendants have failed to maintain sanitation control records to document monitoring and corrections, in violation of 21 C.F.R. § 123.11(c); and

f. The defendants have failed to develop and implement adequate written verification procedures to ensure that the seafood products that the firm imports have been processed under

conditions that comply with the seafood HACCP regulations, in violation of 21 C.F.R. § 123.12.

THE SEPTEMBER-OCTOBER 2006 INSPECTION

33. FDA previously inspected Congressional on September 25-October 3, 2006. During that inspection, FDA investigators documented conditions similar to those listed above and issued a Form FDA-483 to the defendants that identified the violative conditions, including, but not limited to, the following:

a. The defendants did not have a written HACCP plan that outlined controls for a food safety hazard, such as pathogen growth, during storage and shipping of multiple frozen products, in violation of 21 C.F.R. § 123.6(b);

b. The defendants failed to implement appropriate corrective actions after deviations from a critical limit occurred, in violation of 21 C.F.R. § 123.7;

c. The defendants failed to monitor sanitation conditions and practices during processing with sufficient frequency or accuracy to ensure compliance with current good manufacturing practice requirements under 21 C.F.R. § 110, in violation of 21 C.F.R. § 123.11(b);

d. The defendants failed to develop and implement written verification procedures adequate to ensure that the products that the firm imports have been processed under conditions that comply with the seafood HACCP regulations, in violation of 21 C.F.R. § 123.12(a);

e. The defendants failed to manufacture and package foods under conditions and controls necessary to minimize contamination, in violation of 21 C.F.R. § 110.80(b)(2); and

f. The defendants failed to review critical control point monitoring records to ensure that the records were complete and to verify that the recorded values were within critical limits, in violation

of 21 C.F.R. § 123.8(a)(3).

THE MAY 2005 AND SEPTEMBER 2004 INSPECTIONS

34. FDA previously inspected the defendants' firm on May 10-12, 2005 and September 8-9, 2004. During these inspections, FDA documented conditions that were the same as or similar to those listed above. These violative practices include, but are not limited to, the following:

a. The defendants failed to document corrective actions after deviations from a critical limit occurred, in violation of 21 C.F.R. § 123.7(d);

b. The defendants failed to review critical control point monitoring records to ensure that the records were complete and to verify that they document values that were within critical limits, in violation of 21 C.F.R. § 123.8(a)(3); and

c. The defendants did not implement the verification procedures listed in Congressional's HACCP plan, in violation of 21 C.F.R. § 123.6(b); and

d. The defendants failed to implement written verification procedures for ensuring that fish imported by Congressional have been processed under conditions that comply with the seafood HACCP regulations, in violation of 21 C.F.R. § 123.12.

STATE INSPECTIONS

35. The State of Maryland Department of Health and Mental Hygiene (MDHMH) previously inspected Congressional on June 24, 2008; January 23, 2007; August 10, 2004; January 7, 2004; and December 10, 2003 under contract with FDA. During each of these inspections, MDHMH investigators documented conditions that were the same as or similar to those listed above.

36. MDHMH investigators observed violative practices including, but not limited to: the failure

to have temperature records for critical control points for all seafood products; the failure to have monitoring records for the critical control points of histamine prone fish and shellfish products; the failure to calibrate thermometers; the failure to perform an annual review of Congressional's HACCP plans; the failure to monitor the protection of seafood from adulterants; and sanitation deviations.

HISTORY AND PREVIOUS WARNINGS

37. The defendants are well aware that their practices violate the Act. On numerous occasions, FDA has warned the defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of their compliance with the Act.

38. At the conclusion of each of the four violative FDA inspections of Congressional, FDA investigators issued a Form FDA-483 to Thomas P. Spencer or Jonathan D. Pearlman, and discussed the violative conditions with the respective recipient.

39. On January 30, 2007, the FDA Baltimore District Office issued a Warning Letter to the defendants. That letter addressed their numerous HACCP violations, which the FDA investigators observed during the September-October 2006 FDA inspection.

40. On August 9, 2005, the FDA Baltimore District Office issued an Untitled Letter to the defendants. That letter addressed the defendants' numerous HACCP violations observed during the May 2005 FDA inspection.

41. On December 18, 2003, MDHMH issued a Notice of Violation letter to the defendants. That letter addressed the defendants' numerous HACCP violations observed during the December 2003 MDHMH inspection.

42. Despite the numerous warnings from FDA and MDHMH over six years, and the repeated

promises by the defendants to correct their deficiencies, the defendants continue to violate the Act, as demonstrated by the results of FDA's most recent inspection of Congressional.

43. Based on the defendants' course of conduct, the United States is informed and believes that, unless restrained by order of the Court, the defendants will continue to violate 21 U.S.C. §§ 331(a) and (k).

PRAYER FOR RELIEF

WHEREFORE, based on the foregoing, the Plaintiff prays:

I. That the defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly:

a. Violating 21 U.S.C. § 331(a) by introducing or causing to be introduced into interstate commerce, or delivering or causing to be delivered for introduction into interstate commerce, any article of food within the meaning of 21 U.S.C. § 321(f) that is adulterated; and

b. Violating 21 U.S.C. § 331(k) by causing any article of food to become adulterated while such article of food is held for sale after shipment in interstate commerce.

II. That the Court order the defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, to cease preparing, packing, holding, and distributing all seafood products at or from Congressional's Jessup, Maryland location, or at any other location(s) from which the defendants prepare, pack, hold and distribute food, unless and until the defendants bring their preparing, packing,

holding, and distribution operations into compliance with the Act and FDA regulations.

III. That the Court award the Plaintiff its costs incurred in pursuing this action, including the costs of investigation to date, and such other relief as the Court may deem just and proper.

Dated this 21st day of December, 2009

Respectfully submitted,

Rod J. Rosenstein
United States Attorney

By: /s/
Jason D. Medinger (Bar No. 28470)
Assistant United States Attorney
36 South Charles Street
Fourth Floor
Baltimore, Maryland 21201
(410) 209-4800

Of Counsel:
LAUREN H. BELL
Office of Consumer Litigation
United StatesDepartment of Justice
Civil Division
P.O. Box 386
Washington, DC 20044
Phone: (202) 353-1001
Lauren.hash.bell@usdoj.gov

DAVID S. CADE
Acting General Counsel

MICHAEL M. LANDA
Acting Chief Counsel
Food and Drug Division

ERIC M. BLUMBERG

Deputy Chief Counsel for Litigation

VERÓNICA A. WONG
Trial Attorney
U.S. Department of Health and
Human Services
Office of the General Counsel
5600 Fishers Lane
Rockville, MD 20857